

500

Notice of Allowability	Application No.	Applicant(s)	
	09/760,274	SINDEN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9-27-05.
2. ☒ The allowed claim(s) is/are 57-62,64 and 76-86.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/043,061.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Glen Ladwig on 12-9-05.

Claims 1-56, 63 and 65-75 have been canceled. Claims 57-62, 64 and 76-86 remain pending.

The application has been amended as follows:

57. A method for treating brain damage in a mammal, said method comprising intracerebrally transplanting pluripotent, nestin-positive, neuroepithelial cells into the damaged part of the brain of said mammal, wherein said cells have been genetically modified to be conditionally immortal, wherein said cells are immortal prior to said transplanting and differentiate after said transplanting, and wherein said transplanting improves brain function of said mammal.

58. The method of claim 57, wherein the brain damage is in the hippocampus of said mammal.

62. The method of claim 57, wherein the brain damage is the result of hypoxia.

76. The method of claim 57, wherein the brain damage causes a cognitive deficit, and wherein said transplanting improves cognitive function of said mammal.

Art Unit: 1632

81. A method for treating brain damage in a mammal, said method comprising intracerebrally transplanting human pluripotent, nestin-positive, neuroepithelial cells into the damaged part of the brain of said mammal, wherein said human pluripotent, nestin-positive, neuroepithelial cells comprise a temperature-sensitive simian virus 40 large T antigen gene, and wherein said transplanting improves brain function of said mammal.

85. A method for treating brain damage in the hippocampus of a mammal, said method comprising intracerebrally transplanting human pluripotent, nestin-positive, neuroepithelial cells into the damaged hippocampus of said mammal, wherein said human pluripotent, nestin-positive, neuroepithelial cells comprise a temperature-sensitive simian virus 40 large T antigen gene, and wherein said transplanting improves cognitive function of said mammal.

The following is an examiner's statement of reasons for allowance:

Priority

The instant application and parent application 09/043061 have the same disclosure.

This application repeats a substantial portion of prior Application No. 09/537617, filed 3-29-00, now US Patent 6,569,421, and adds and claims additional disclosure not presented in the prior application. The instant application does not claim priority to 09/537617.

Claim Rejections - 35 USC § 112**Written Description**

The rejection of claims 57, 58, 60-62, 64 and 76-86 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn.

The written description rejection regarding obtaining human pluripotent neuroepithelial cells equivalent to the mouse cells exemplified by applicants has been withdrawn in view of applicants' arguments. In particular, applicants argue musashi 1 is not essential to identify human pluripotent neuroepithelial cells capable of treating brain damage and is equivalent to use of nestin (pg 8 of appeal brief). Applicants also point to pg 13, lines 5-7, which teaches that the "precise time (stage and development)" that the cells are obtained may vary.

New Matter

The rejection regarding the phrase "a disorder associated with damage to, or loss of, brain cells in a mammal" in claims 57, 81 and 85 has been withdrawn in view of the examiner's amendment.

The rejection regarding the phrase "a disorder associated with damage to, or loss of, brain cells in the hippocampus of said mammal" in claim 58 has been withdrawn in view of the examiner's amendment.

Enablement

The rejection of claims 57, 58, 60-62 and 76-86 under 35 U.S.C. 112, first paragraph, enablement, has been withdrawn in view of the examiner's amendment.

The enablement rejection regarding obtaining human pluripotent neuroepithelial cells equivalent to the mouse cells exemplified by applicants has been withdrawn in view of applicants' arguments. In particular, applicants argue musashi 1 is not essential to identify human pluripotent neuroepithelial cells capable of treating brain damage and is equivalent to use of nestin (pg 8 of appeal brief). Applicants also point to pg 13, lines 5-7, which teaches that the "precise time (stage and development)" that the cells are obtained may vary.

The enablement rejection regarding treating brain damage in humans has been withdrawn because the specification enables obtaining human pluripotent neuroepithelial cells capable of treating brain damage.

The enablement rejection regarding treating diseases "associated" with brain damage has been withdrawn in view of the examiner's amendment.

The enablement rejection regarding the breadth of "conditionally immortal" cells has been withdrawn in view of applicants' arguments (pg 25-26 of appeal brief).

Double Patenting

The provisional double patenting rejections over US applications 10/342,692 and 10/376,119 have been withdrawn because the applications have not issued.

Art Unit: 1632

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent application 11/178,216

Claims 57-62, 64 and 76-86 have been allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**